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| APPLICATION NO.  | FILING DATE    | FIRST NAMED INVENTOR              | ATTORNEY DOCKET NO.     | CONFIRMATION NO. |
|--|----------------|-----------------------------------|-------------------------|------------------|
| 09/513,999   | 02/24/2000     | Jean-Baptiste Dumas Milne Edwards | G-059US02REG            | 6082             |
| 23557 759  | 90 06/17/2003  |                                   |                         |                  |
| SALIWANCHIK LLOYD & SALIWANCHIK A PROFESSIONAL ASSOCIATION 2421 N.W. 41ST STREET |                |                                   | EXAMINER                |                  |
|  |                |                                   | MARTINELL, JAMES        |                  |
| SUITE A-1  |                | V                                 |                         |                  |
| GAINESVILLE  | , FL 326066669 | ,                                 | ART UNIT                | PAPER NUMBER     |
|  |                | \                                 | 1631                    | 16.              |
|  |                | ì                                 | DATE MAILED: 06/17/2003 | •                |

Please find below and/or attached an Office communication concerning this application or proceeding.

| •   |  |                                    |  |  |  |  |
|---|--|------------------------------------|--|--|--|--|
| Office Action Summary   |  | Application No.                    | Applicant(s)                                       |  |  |  |
|   |  | 09/513,999                         | EDWARDS ET AL.                                     |  |  |  |
|   |  | Examiner                           | Art Unit   |  |  |  |
|   |  | James Martinell                    | 1631   |  |  |  |
| Period fo   | The MAILING DATE of this communication app<br>or Reply   | ears on the cover sheet with the ( | correspondence address                             |  |  |  |
| A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.  - Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.  - If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.  - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.  - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).  - Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b). |  |                                    |  |  |  |  |
| 1)⊠   | Responsive to communication(s) filed on 10 A   | pril 2003 .                        |  |  |  |  |
| 2a) <u></u>   |  | s action is non-final.             |  |  |  |  |
| 3)  | Since this application is in condition for allowa  | nce except for formal matters, p   | rosecution as to the merits is                     |  |  |  |
| closed in accordance with the practice under <i>Ex parte Quayle</i> , 1935 C.D. 11, 453 O.G. 213. <b>Disposition of Claims</b>  |  |                                    |  |  |  |  |
| 4)⊠ Claim(s) <u>61-84</u> is/are pending in the application.  |  |                                    |  |  |  |  |
| 4a) Of the above claim(s) is/are withdrawn from consideration.  |  |                                    |  |  |  |  |
| 5)⊠   | 5)⊠ Claim(s) <u>61,63 and 65</u> is/are allowed.   |                                    |  |  |  |  |
| 6)⊠   | 6)⊠ Claim(s) <u>62,67,79-81, 83, and 84</u> is/are rejected.   |                                    |  |  |  |  |
| 7)🖂   | Claim(s) <u>64, 66, 68-78, and 82</u> is/are objected to   | 0.                                 |  |  |  |  |
| 8) Claim(s) are subject to restriction and/or election requirement.  Application Papers   |  |                                    |  |  |  |  |
| 9)☐ The specification is objected to by the Examiner.   |  |                                    |  |  |  |  |
| 10)☐ The drawing(s) filed on is/are: a)☐ accepted or b)☐ objected to by the Examiner.   |  |                                    |  |  |  |  |
| Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).   |  |                                    |  |  |  |  |
| 11) ☐ The proposed drawing correction filed on is: a) ☐ approved b) ☐ disapproved by the Examiner.  |  |                                    |  |  |  |  |
| If approved, corrected drawings are required in reply to this Office action.  |  |                                    |  |  |  |  |
| 12)☐ The oath or declaration is objected to by the Examiner.  |  |                                    |  |  |  |  |
| Priority under 35 U.S.C. §§ 119 and 120   |  |                                    |  |  |  |  |
| 13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).   |  |                                    |  |  |  |  |
| a) ☐ All b) ☐ Some * c) ☐ None of:  |  |                                    |  |  |  |  |
| 1. Certified copies of the priority documents have been received.   |  |                                    |  |  |  |  |
|   | 2. Certified copies of the priority documents have been received in Application No   |                                    |  |  |  |  |
| <ul> <li>3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).</li> <li>* See the attached detailed Office action for a list of the certified copies not received.</li> </ul>   |  |                                    |  |  |  |  |
| 14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).  |  |                                    |  |  |  |  |
| <ul> <li>a) ☐ The translation of the foreign language provisional application has been received.</li> <li>15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.</li> </ul>   |  |                                    |  |  |  |  |
| Attachment(s)   |  |                                    |  |  |  |  |
| 2) Notice   | of References Cited (PTO-892)<br>of Draftsperson's Patent Drawing Review (PTO-948)<br>nation Disclosure Statement(s) (PTO-1449) Paper No(s) <u>3</u> . |                                    | (PTO-413) Paper No(s) Patent Application (PTO-152) |  |  |  |
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Applicant's election without traverse of Group I, claims 1-12, 18-33, 39-43, and 55-58 and SEQ ID NO: 3792 which encodes SEQ ID NO: 7869 in Paper No. 15 is acknowledged. It is noted that applicants have cancelled claims 1-60 and submitted new claims 61-84, which new claims correspond to the elected invention.

Claims 64, 66, and 68-78 are objected to under 37 CFR 1.75(c) as being in improper form because a multiple dependent claim should refer to other claims in the alternative only. See MPEP § 608.01(n). Accordingly, the claims have not been further treated on the merits.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 62 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

(a) Claim 62 is vague and indefinite because the preamble of the claim seems to claim a signal peptide sequence while the rest of the claim and claim 61 (from which claim 62 depends) are drawn to polynucleotides.

Claim 67 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The instant application does not adequately describe a gene that corresponds to SEO ID NO: 3792.

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claim 84 is rejected under 35 U.S.C. 101 because the claimed invention lacks patentable utility. The claimed invention lacks patentable utility because the instant application does not disclose any activity or specific, substantial, and credible utility for any polypeptide encoded by SEQ ID NO: 3792. Thus, a method for making the polypeptide encoded by SEQ ID NO: 3792 has no patentable utility.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 79-81 and 83 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by Maclaren et al (U.S. 5,376,533 (December 27, 1994)). Maclaren et al discloses a primer that contains 18 contiguous nucleotides of SEQ ID NO: 3792 (compare SEQ ID NO: 1, positions 8-25 to SEQ ID NO: 3792, positions 288-305 and the alignment attached to the copy of the reference). In addition, Maclaren et al (*e.g.*, see column 6) discloses a method of making cDNAs using the primer that is SEQ ID NO: 1, with or without the use of additional primers, that is embraced by the claims.

Claim 82 is objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Claims 61, 63, and 65 are allowable over the prior art of record.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to James Martinell whose telephone number is (703) 308-0296. The fax phone number for Examiner Martinell's desktop workstation is (703) 746-5162. The examiner works a flexible schedule and can be reached by phone and voice mail. Alternatively, a request for a return telephone call may be e-mailed to james.martinell@uspto.gov. Since e-mail communications may not be secure, it is suggested that information in such requests be limited to name, phone number, and the best time to return the call.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward, can be reached on (703) 305-4028. The fax phone number for the organization where this application or proceeding is assigned is (703) 308-4242.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

James Martinell, Ph.D. Primary Examiner Art Unit 1631 Page 4